

AMENDMENTS TO THE CLAIMS

Claims 1-36 canceled

37. (New) A pharmaceutical composition for oral administration of saquinavir comprising:

- (i) saquinavir or its pharmaceutical acceptable salts as the active ingredient in a concentration ranging from 10% to 80% in weight of the final composition;
- (ii) a long chain fatty acid of C₁₂₋₁₈ in a concentration ranging from 20% to 80% in weight of the final composition;
- (iii) at least an alcohol of chain C₂₋₄ in a concentration ranging from 2% to 20% in weight of the final composition;
- (iv) a non-ionic surfactant in a concentration ranging from 0.1% to 30% in weight of the final composition;
- (v) a pharmaceutical acceptable antioxidant in a concentration ranging from 0.001% to 2.0% in weight of the final composition.

38. (New) The pharmaceutical composition of claim 37, wherein saquinavir, or its pharmaceutical acceptable salts, is employed in a concentration ranging from 15% to 70% in weight of the final composition.

39. (New) The pharmaceutical composition of claim 37, wherein the fatty acid of C₁₂₋₁₈ is oleic acid, used in a concentration ranging from 20% to 70% in weight of the final composition.

40. (New) The pharmaceutical composition of claim 37, wherein the alcohol of C₂₋₄ is ethanol or propyleneglicol or mixtures thereof, in a concentration ranging from 2% to 20% in weight of the final composition.

41. (New) The pharmaceutical composition of claim 37, wherein the non-ionic surfactant is selected among polyethoxylated derivatives from castor oil and polyoxyethylene sorbitan esters (polysorbates) in a concentration ranging from 0.1% to 30% in weight of the final composition.

42. (New) The pharmaceutical composition of claim 41, wherein the polyethoxylated derivatives from castor oil are polyethoxylated castor oil 35 (Cremophor EL) or polyethoxylated hydrogenated castor oil 40 (Cremophor RH 40), in a concentration ranging from 0.1% to 30% in weight of the final composition.

43. (New) The pharmaceutical composition of claim 41, wherein the polyoxyethylene sorbitan esters are the liquid polysorbates like as polysorbate 20, 40, 60 and 80, in a concentration ranging from 0.1% to 30% in weight of the final composition.

44. (New) The pharmaceutical composition of claim 37, wherein the pharmaceutical acceptable antioxidant is alpha-tocopherol or butylated hidroxytoluene, in a concentration ranging from 0.001% to 2.0% in weight of the final composition.

45. (New) The pharmaceutical composition according to claim 37, characterized by consisting of a stable concentrate microemulsion wherein the active ingredient saquinavir, or its pharmaceutical acceptable salts, is soluble.

46. (New) The pharmaceutical composition of claim 45, which is fractionated in single doses in the form of soft gelatin capsules for oral administration in the treatment of AIDS.

47. (New) The pharmaceutical composition according to claim 45, which is fractionated in single doses in the form of hard gelatin capsules for oral administration in the treatment of AIDS.

48. (New) The pharmaceutical composition according to claim 37 in which the bioavailability of saquinavir, when measured by AUC and C_{max} parameters, is at least 5 times higher than the same dosage from the reference composition.

49. (New) A process for preparing a pharmaceutical composition for oral administration of saquinavir in accordance with the claim 37 which comprises the following steps:

- (a) Completely dissolving saquinavir, or its pharmaceutical acceptable salt, in a sufficient amount of the alcohol of C_{2-4} under controlled temperature;
- (b) Eliminating particles by filtration;
- (c) Adding the fatty acid of chain C_{12-18} , the antioxidant and the non-ionic surfactant in an appropriate amount used in the composition;
- (d) Evaporating the alcohol at a maximum temperature of 50°C under reduced pressure;
- (e) Optionally, adding the non-ionic surfactant from step (c) after the evaporation of the alcohol from step (d);
- (f) Adding the alcohol C_{2-4} under stirring and in an enough amount to complete the adequate weight of the final composition;
- (g) Resulting in the final composition in the form of a stable concentrate microemulsion wherein the saquinavir form is soluble.

50. (New) The process of claim 49, wherein in step (a) saquinavir, or its pharmaceutical acceptable salts, is in the crystalline, amorphous, micronized or mixtures of that forms, in a concentration ranging from 0.01% to 90% in weight of the final solution.

51. (New) The process of claim 49, wherein the alcohol of chain C₂₋₄ in step (a) is used in a concentration ranging from 10% to 99.99% in weight of the final solution.
52. (New) The process of claim 51, wherein the alcohol of chain C₂₋₄ is ethanol.
53. (New) The process according with claim 49, wherein the temperature in step (a) ranges from 20°C to 50°C.
54. (New) The process of claim 49, wherein the fatty acid of chain C₁₂₋₁₈ used in step (c) is oleic acid.
55. (New) The process of claim 49, wherein the antioxidant used in step (c) is tocopherol, butylated hydroxytoluene or mixtures thereof.
56. (New) The process of claim 49, wherein the non-ionic surfactant used in step (c) or (e) is selected among polyethoxylated derivatives from castor oil and polyoxyethylene sorbitan esters (polysorbates).
57. (New) The process of claim 56, wherein the non-ionic surfactant used in step (c) or (e) is polyethoxylated castor oil 35 (Cremophor EL) or polyethoxylated hydrogenated castor oil 40 (Cremophor RH 40).
58. (New) The process of claim 56, wherein the non-ionic surfactant used in step (c) or (e) is a liquid polysorbate like as polysorbate 20, 40, 60 and 80.
59. (New) The process of claim 49, wherein the alcohol of chain C₂₋₄ used in step (f) is ethanol, or propyleneglycol, or mixtures thereof.

60. (New) The process of claim 49, wherein the resulting product in the step (g) presents saquinavir, or its pharmaceutical acceptable salts, in a concentration ranging from 10% to 80% in weight of the final pharmaceutical composition.

61. (New) The process of claim 60, wherein the resulting product in the step (g) presents saquinavir, or its pharmaceutical acceptable salts, in a concentration ranging from 15% to 70% in weight of the final pharmaceutical composition.

62. (New) The process of claim 60, wherein the resulting product in the step (g) contains the fatty acid of chain C₁₂₋₁₈ in a concentration ranging from 20% to 80% in weight of the final pharmaceutical composition.

63. (New) The process of claim 49, wherein the resulting product in the step (g) contains oleic acid as the fatty acid of chain C₁₂₋₁₈, in a concentration ranging from 20% to 70% in weight of the final pharmaceutical composition.

64. (New) The process of claim 49, wherein the resulting product in the step (g) contains ethanol, or propyleneglycol or mixtures thereof as the alcohol of chain C₂₋₄, in a concentration ranging from 2.0% to 20% in weight of the final pharmaceutical composition.

65. (New) The process of claim 49, wherein the resulting product in the step (g) contains a non-ionic surfactant selected from the group constituted of polyethoxylated castor oil 35 (Cremophor 35), polyethoxylated hydrogenated castor oil 40 (Cremophor RH 40), polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80 or mixtures thereof, in a concentration ranging from 0.1% to 30% in weight of the final pharmaceutical composition.

66. (New) The process of claim 49, wherein the resulting product in the step (g) contains alpha-tocopherol or butylated hydroxytoluene as the antioxidant, in a concentration ranging from 0.001% to 2.0% in weight of the final pharmaceutical composition.

67. (New) The process of claim 49, wherein the resulting product in the step (g) is in a suitable form to be encapsulated in hard or soft gelatin capsules for the oral administration in AIDS treatment.

68. (New) A method to increase bioavailability of saquinavir, or its pharmaceutical acceptable salts, which consists in administering to a patient during the therapy a pharmaceutical composition prepared according to claim 49.